PMI PEPIN MANUFACTURING INC.

APR 2 0 2006

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K060579

510(k) Summary

Company Name:	Pepin Manufacturing, Inc.
	Lake City, MN
Contact:	Jeff Solberg, President
Phone:	651 345-5655
Fax:	651 345-5656
Summary Date:	February 24, 2006
Trade Name:	Iontophoresis Drug Delivery System Electrodes
Common Name:	Comfort/IO Iontophoresis Electrodes
Classification Name:	21 CFR 890.5525, Iontophoresis Device

Predicate Device(s):

510(k) Number:	K031053
Manufacture:	Selective Med Components, Inc.
Trade Name:	Buffered Iontophoresis Drug Delivery System Electrodes
510(k) Number:	K914264, K925800, K933620
Manufacture:	Iomed, Inc.
Trade Name:	Iontophoresis Drug Delivery Electrodes
510(k) Number:	K040495
Manufacture:	North American Industrial Manufacturing Company
Trade Name:	Naimco, Inc. Iontophoresis Drug Delivery Electrodes

1.0 Description of Electrodes

Iontophoresis electrodes described in this application are single patient use, disposable, non-sterile devices. Fundamentally the iontophoresis electrodes consist of two skin contacting electrodes: a drug delivery electrode and a return electrode. When connected to the user's iontophoresis electronic device, the electrodes localize administration of ionic drug solutions into the body for medical purposes.

The electrodes provide the patient contact device. The electrodes are used under the supervision of a physician or other medical professional. The iontophoresis electrodes are intended for use only with approved drugs delivered by iontophoresis technology.

There are variations of sizes and shapes of the drug delivery electrode. The size of the return electrode is constant for all drug delivery electrode variations. The iontophoresis electrodes do not include lead wires. The electrode electrical contact is made by a snap on the electrode.

Iontophoresis electrodes are used under the direct supervision of a physician or medical professional. The electrodes are placed in contact with the skin to support introduction of soluble salts and other dugs into the body.

2.0 Intended Use of Electrodes

The Pepin Manufacturing, Inc. iontophoresis electrodes are intended to be used to introduce soluble salts and other dugs into the body.

3.0 Technological Characteristics

The iontophoresis electrodes do not contain active electronics, software or firmware. The electrodes connect to the user's iontophoresis electronic device. The drug delivery electrode is a buffed gel covered carbon electrode. The return electrode is a buffered hydrogel material electrode. Electrode material biocompatibility is addressed in the submission.

The iontophoresis electrodes have the equivalent technological characteristics to predicate iontophoresis electrodes, including performance specifications, materials, sizes, packaging and labeling. Verification of performance and labeling are provided in the submission.

4.0 Conclusions

The Pepin Manufacturing, Inc. iontophoresis electrodes are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 2006

Pepin Manufacturing, Inc.
c/o Quality & Regulatory Associates, LLC
Mr. Gary Syring
Principal Consultant
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K060579
Trade/Device Name: Comfort/IO Iontophoresis Electrodes
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: III
Product Code: EGJ
Dated: February 24, 2006
Received: March 6, 2006

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the devices as described below. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994, and the enclosed Federal Register, dated August 22, 2000.

If you have any questions regarding this letter, you may contact:

Dora Vega, M.D., Ph.D.
Food and Drug Administration
Center for Devices and Radiological Health
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard (HFZ-410)
Rockville, Maryland 20850
(301) 594-3090

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by

reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): K060579

Device Name: Comfort/IO Iontophoresis Electrodes

Indications for Use:

The Pepin Manufacturing, Inc. iontophoresis electrodes are intended to be used to introduce soluble salts and other dugs into the body.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060579